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Dennis et al.

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(54) **TUBING SYSTEM**

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(73) Assignee: **Linear Health Sciences, LLC**, Norman, OK (US)

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Related U.S. Application Data

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(51) **Int. Cl.**

A61M 39/26 (2006.01)

A61M 39/10 (2006.01)

(52) **U.S. Cl.**

CPC ***A61M 39/26*** (2013.01); ***A61M 39/1011*** (2013.01); *A61M 2039/1027* (2013.01); *A61M 2039/1061* (2013.01)

(58) **Field of Classification Search**

CPC A61M 39/26; A61M 2039/262; A61M 2039/267; A61M 2039/268

See application file for complete search history.

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Primary Examiner — Andrew Gilbert

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(57) **ABSTRACT**

The breakaway assembly includes a first breakaway subassembly and a second breakaway subassembly. The subassemblies are configured to connect, which causes bellows sheaths in each subassembly to compress and open pores, allowing fluid to flow through the subassemblies. The subassemblies can be connected to luer tip. The luer tips can be connected to the an intravenous (IV) fluid line or other types of lines used in the medical field to move fluids. This allows the movement of fluid from a fluid-holding component to a patient. Unless the subassemblies are locked together, the subassemblies will be disconnected under the correct amount of pressure. This disconnection closes the pores on the subassemblies, which keeps fluid from leaking, and prevents the contamination of the IV line. Luer tips may also be connected to the subassemblies. Some of the luer tips allow for the quick connection of the luer tip to the subassembly through a flange being inserted into a notch or flange acceptor. This allows for the quick and easy replacement of components of a fluid transfer assembly.

29 Claims, 26 Drawing Sheets

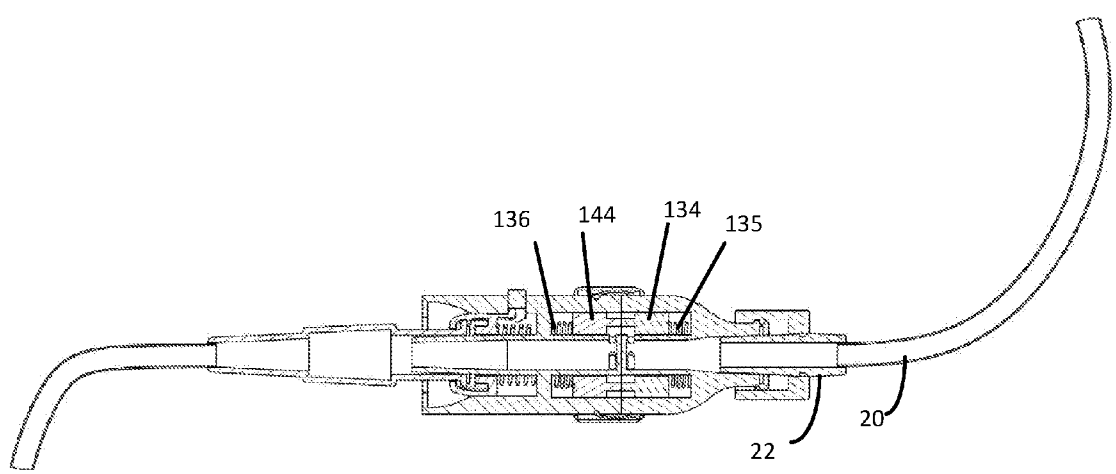

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FIG. 1

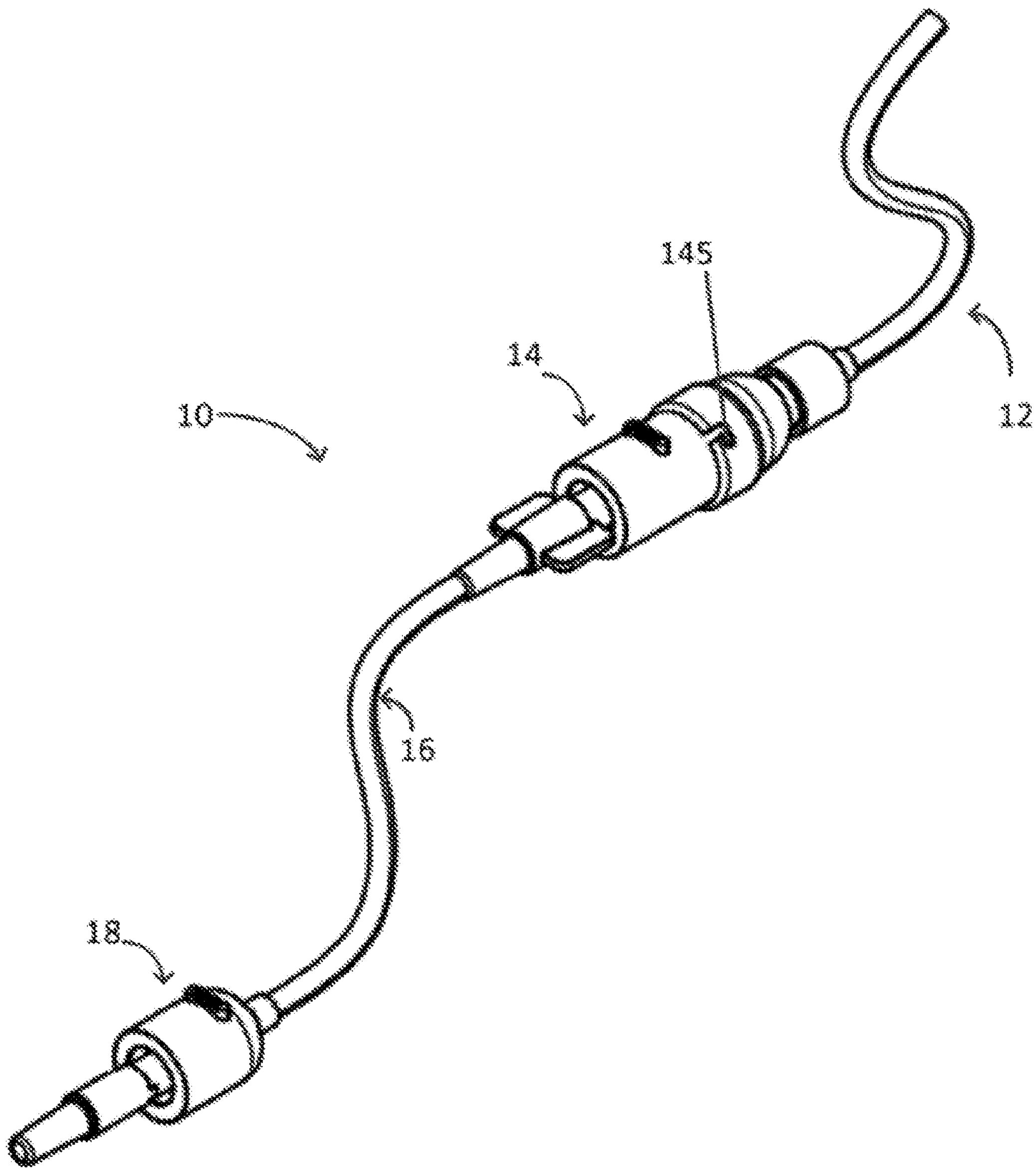

FIG. 2

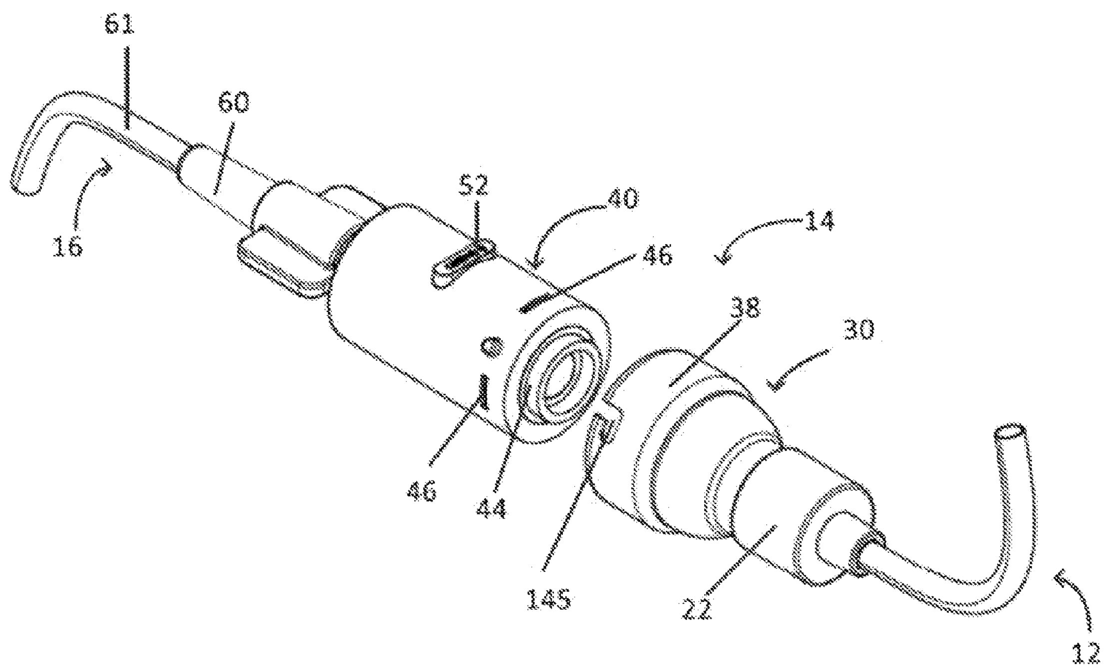

FIG. 3

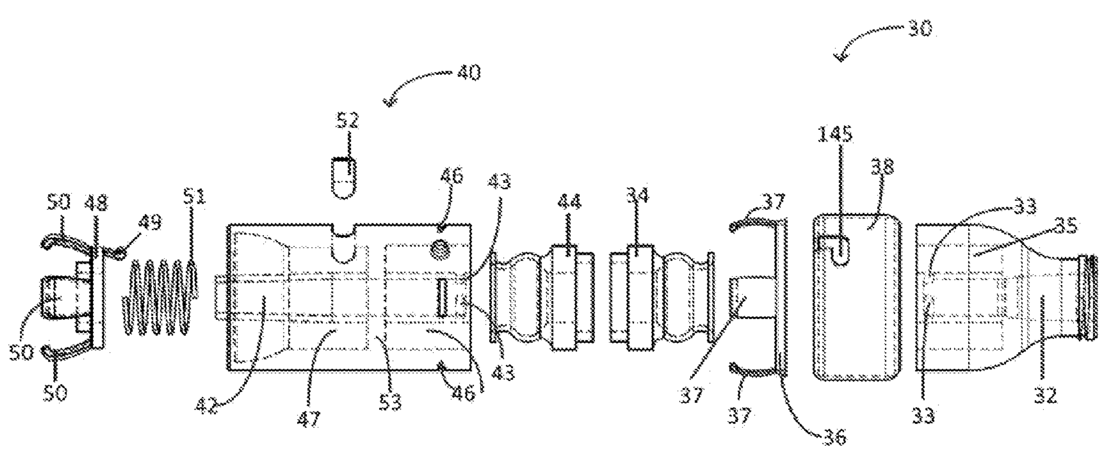
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FIG. 4

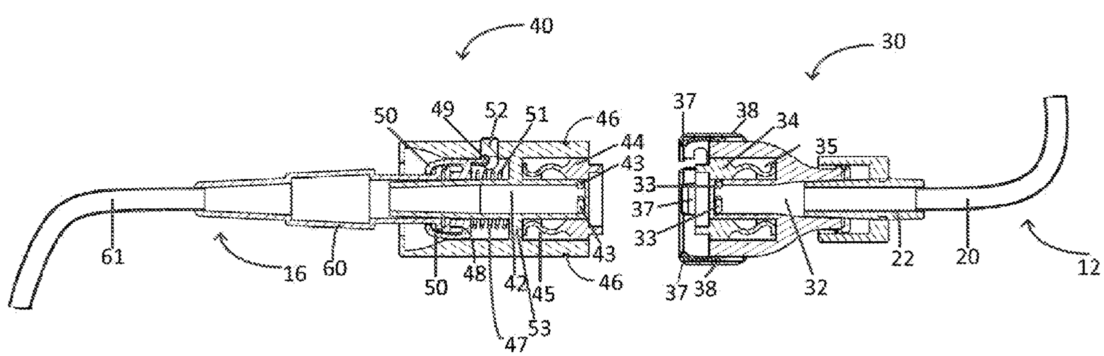
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FIG. 5

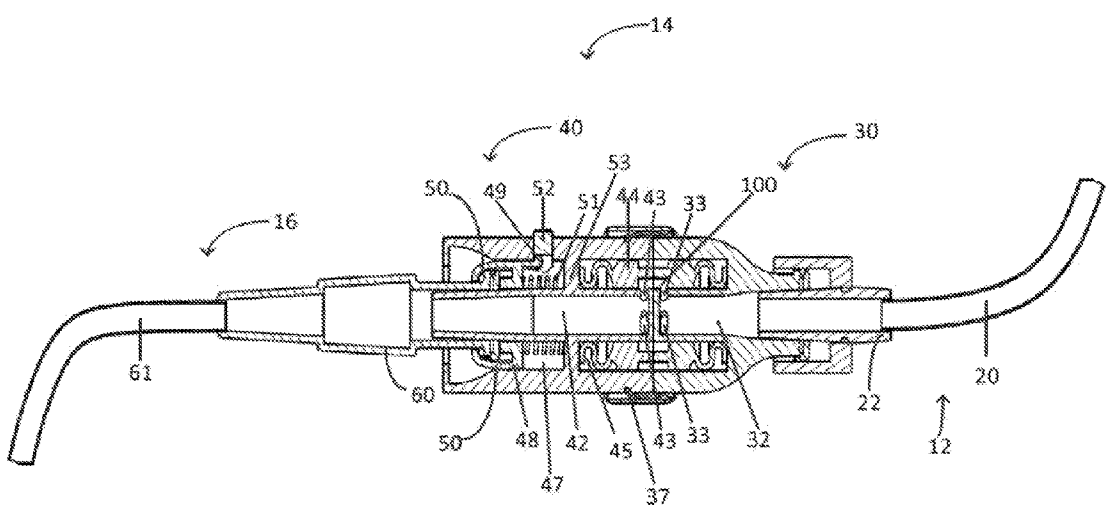

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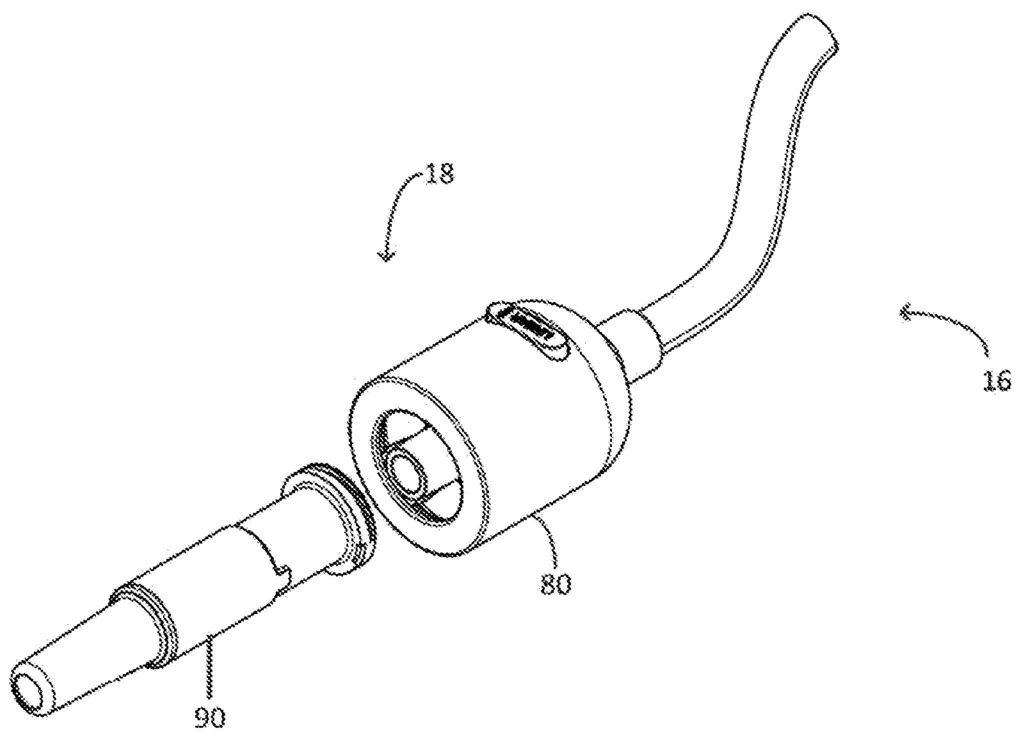
FIG. 6



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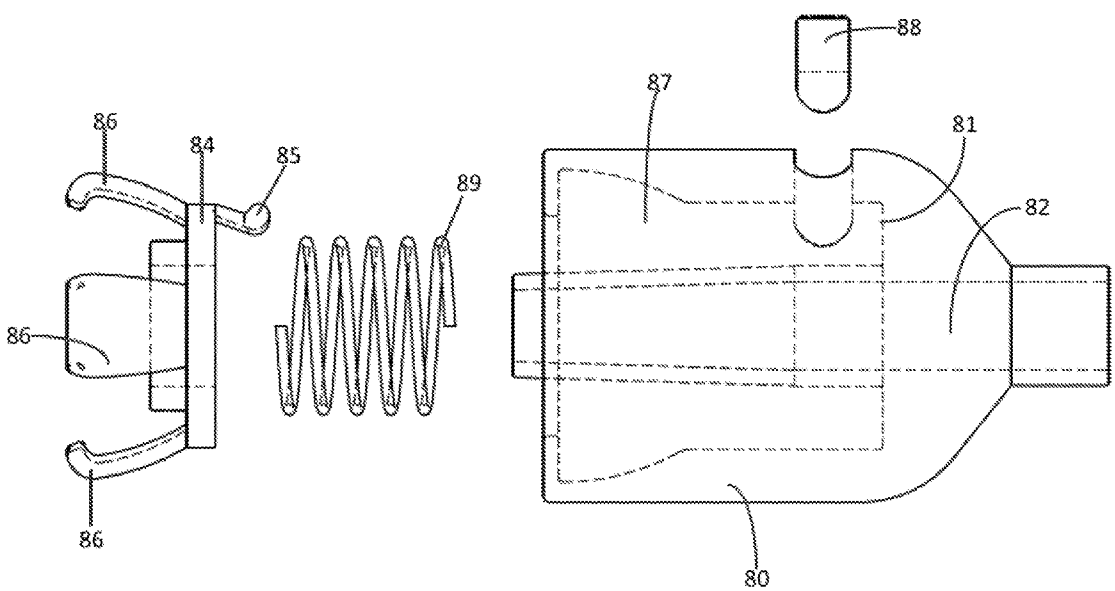

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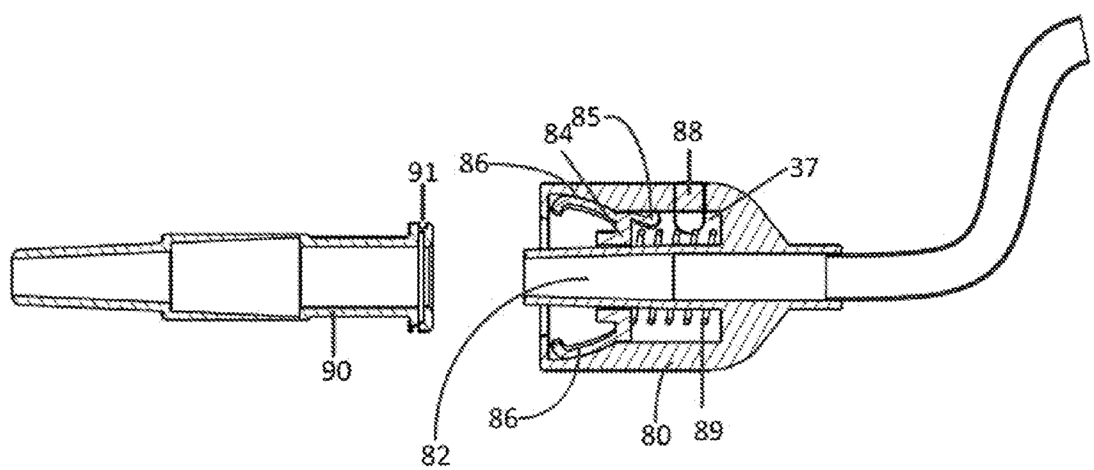

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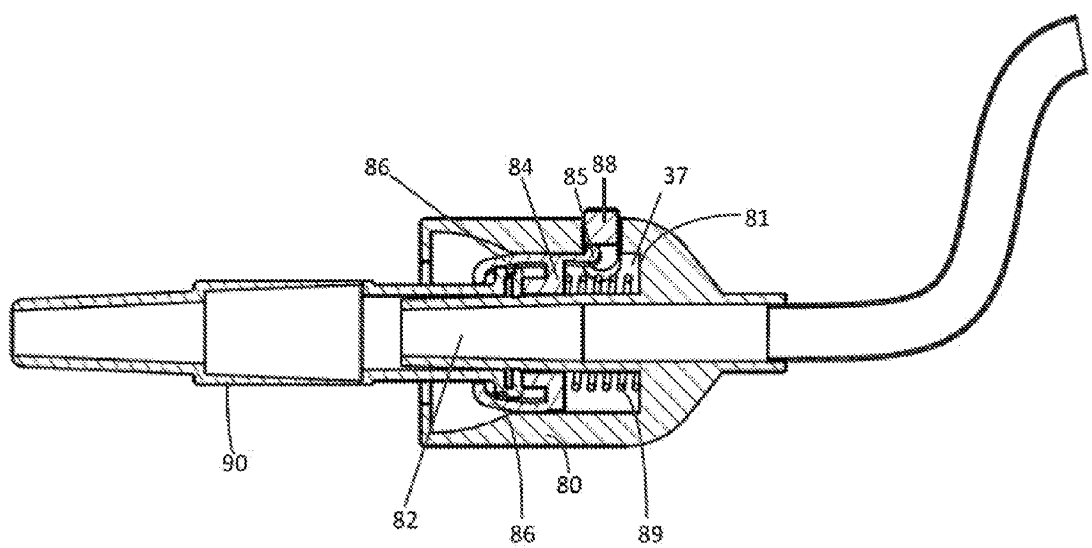

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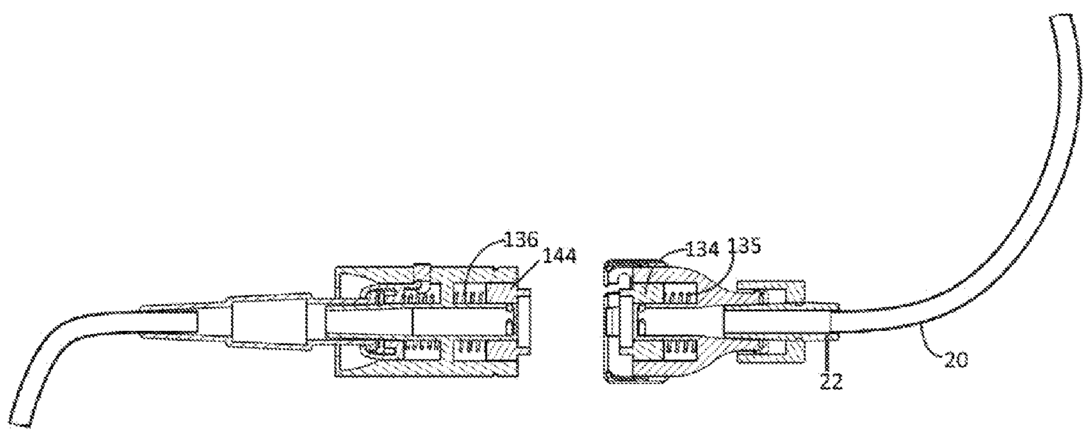

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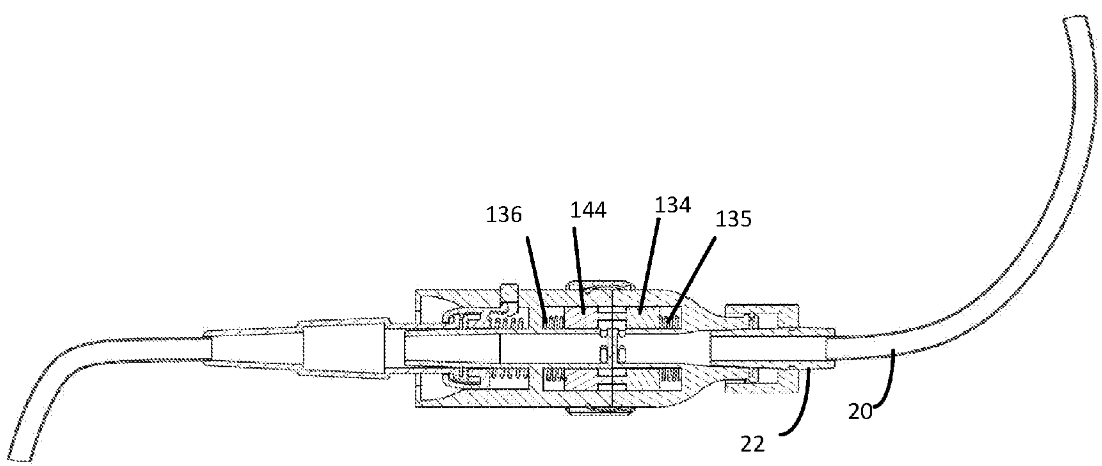

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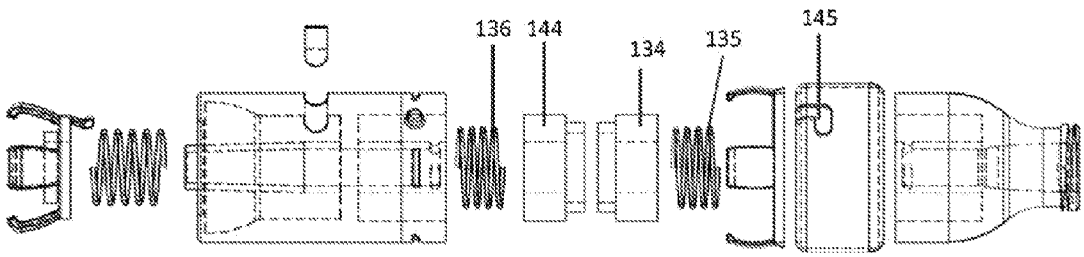

FIG. 13

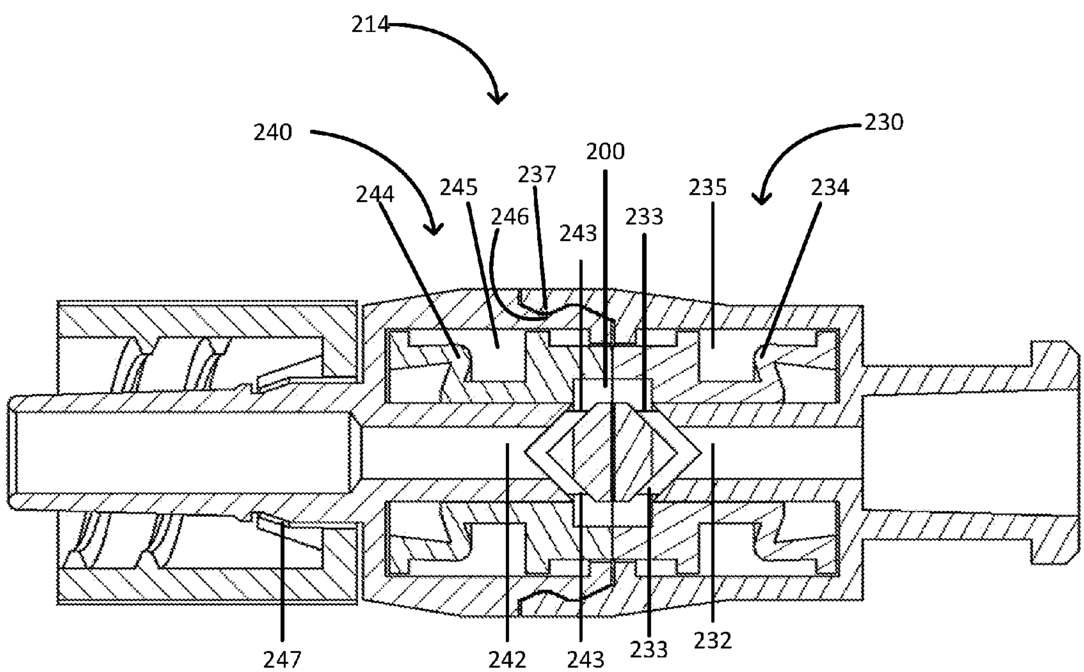
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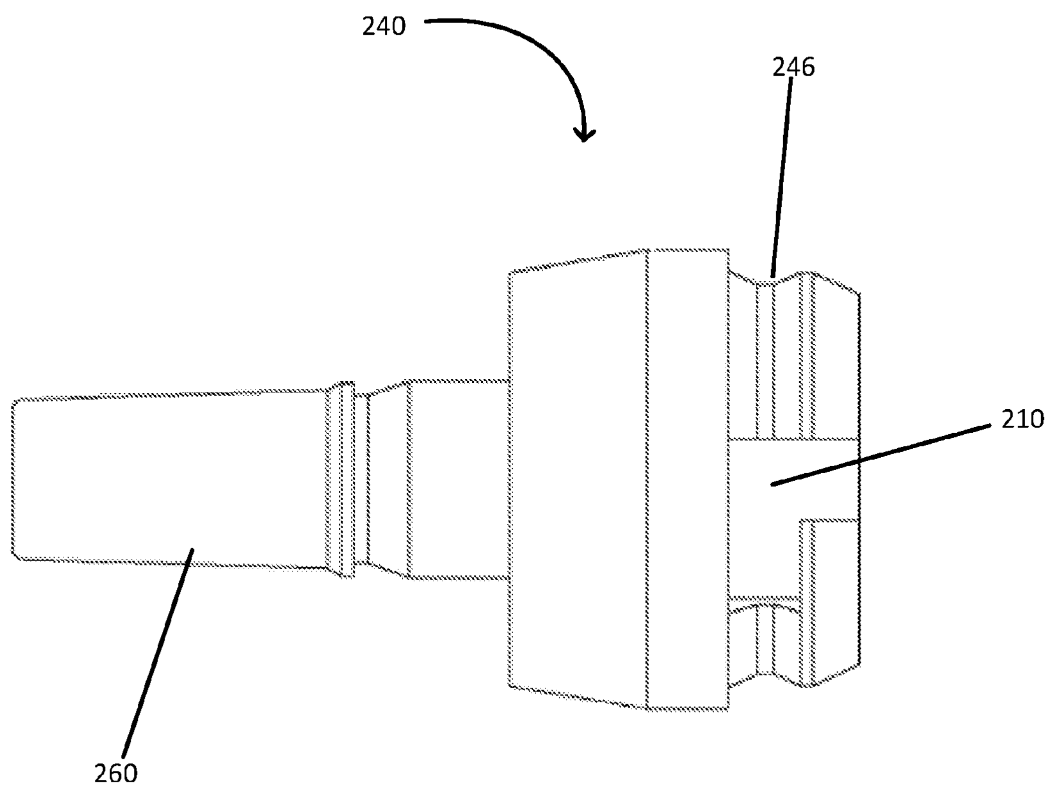
FIG. 14



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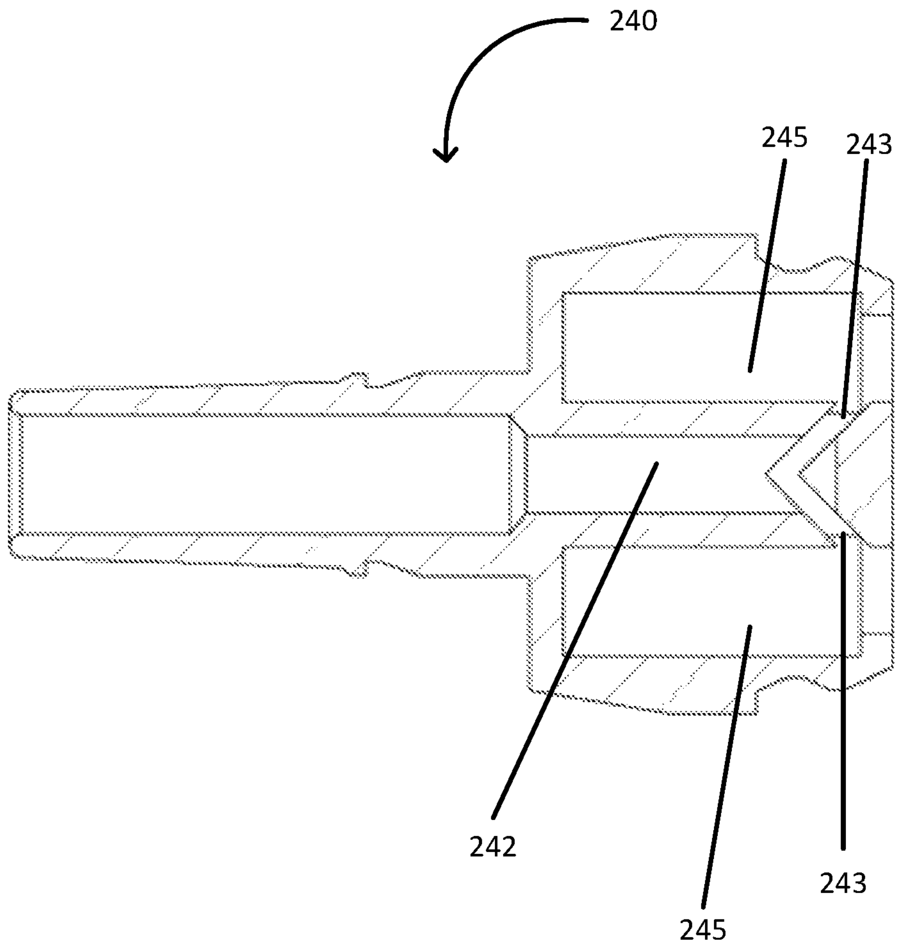


FIG. 16

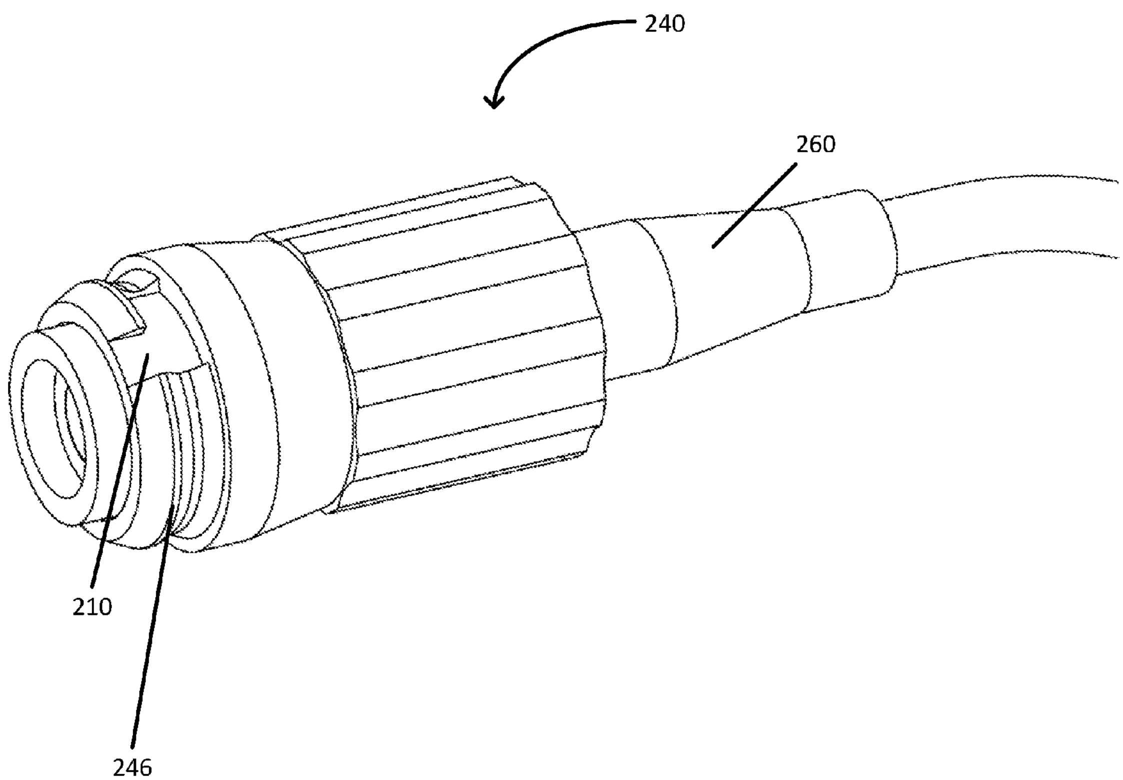


FIG. 17

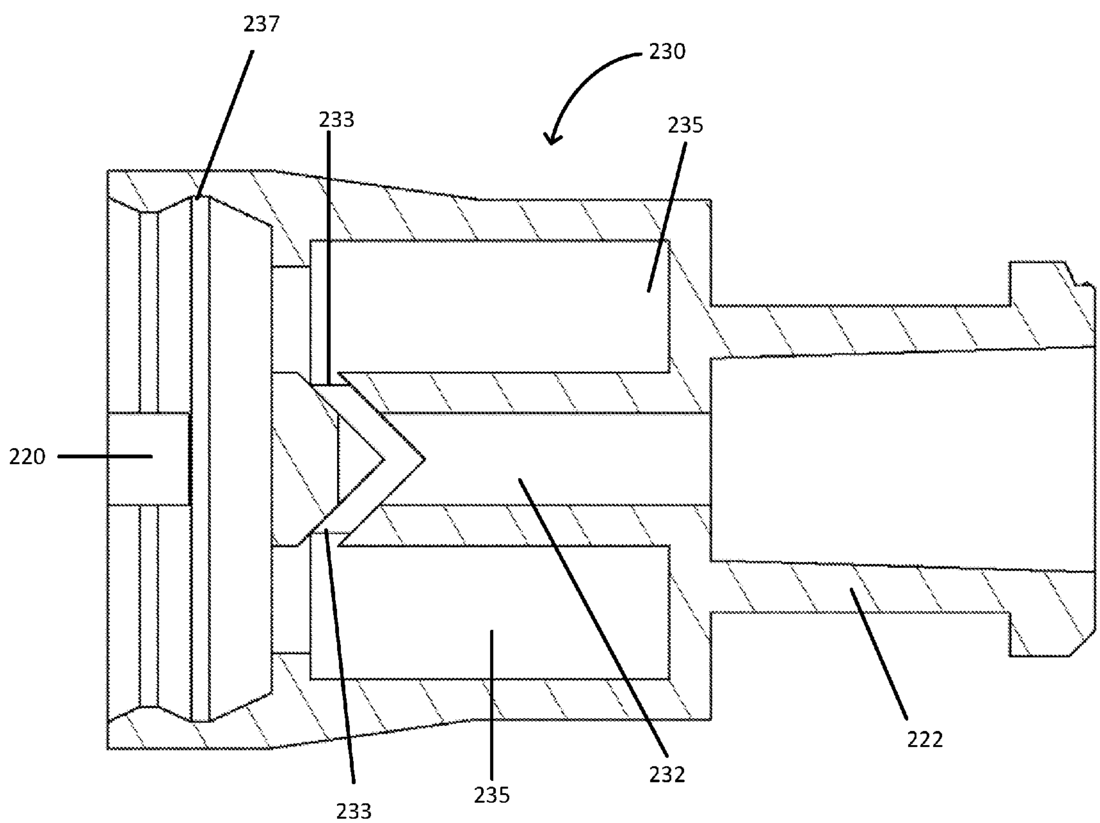
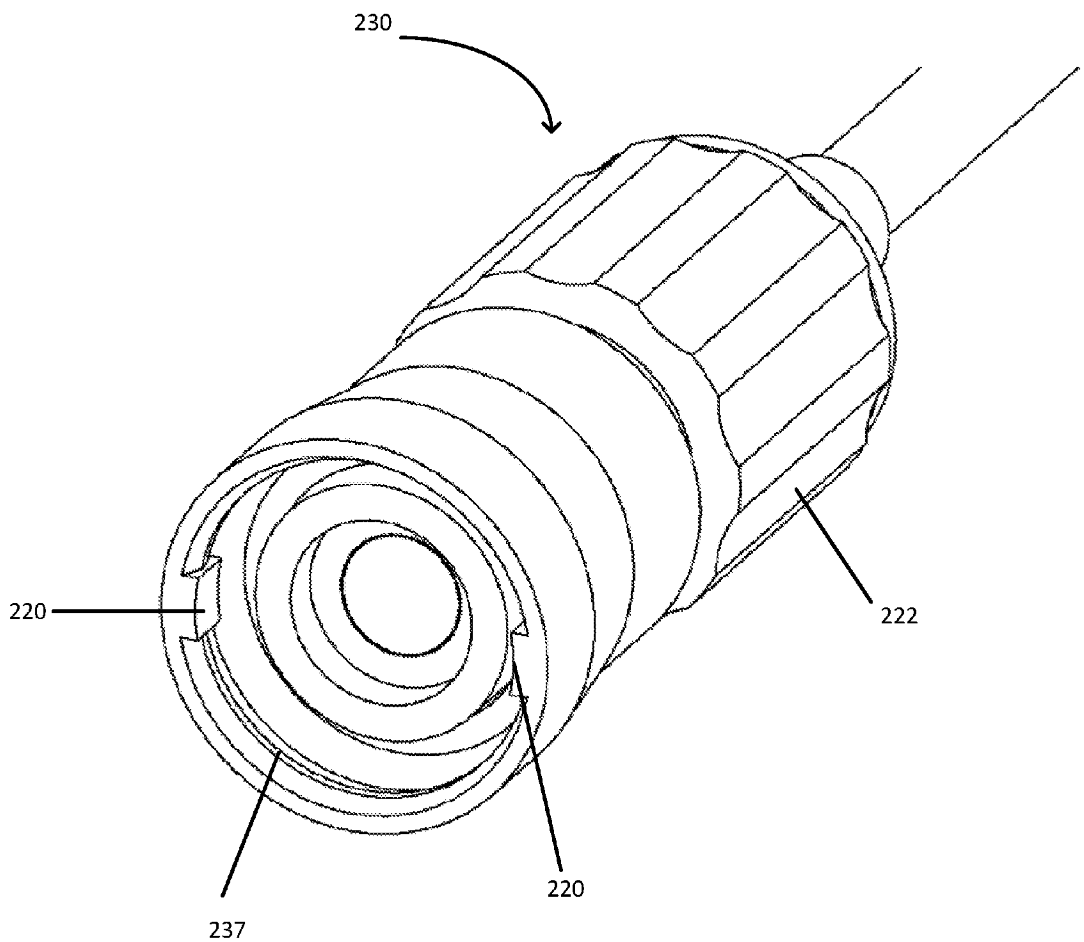


FIG. 18



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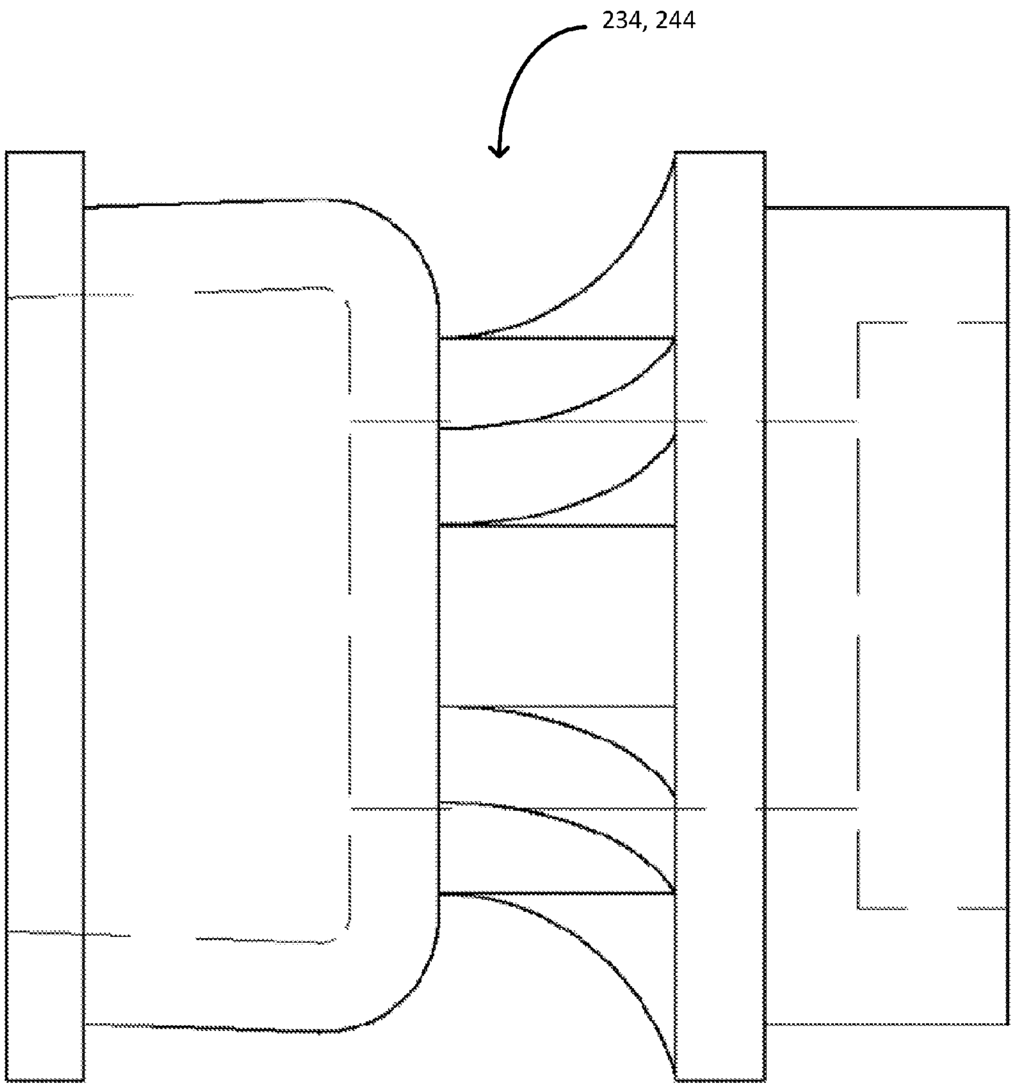

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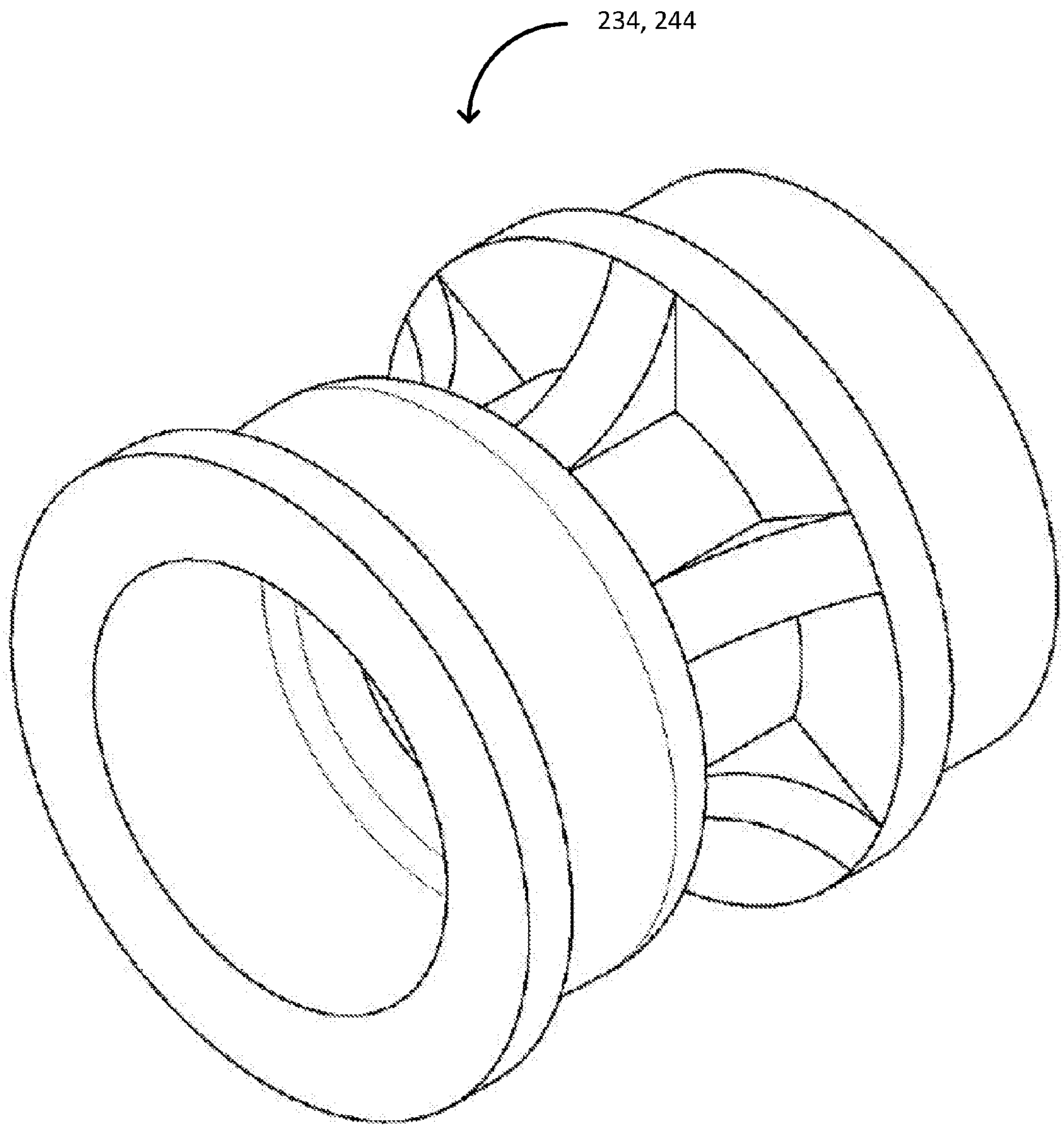

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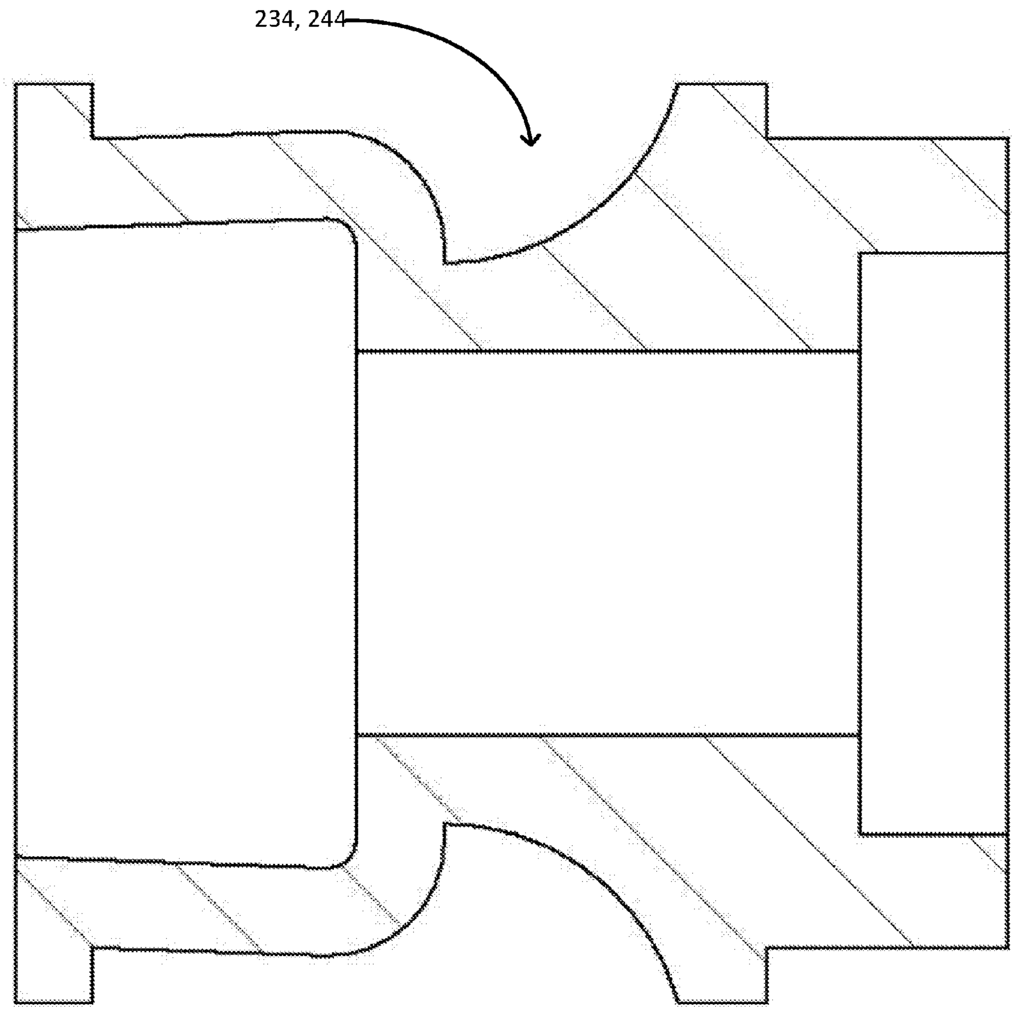

FIG. 22

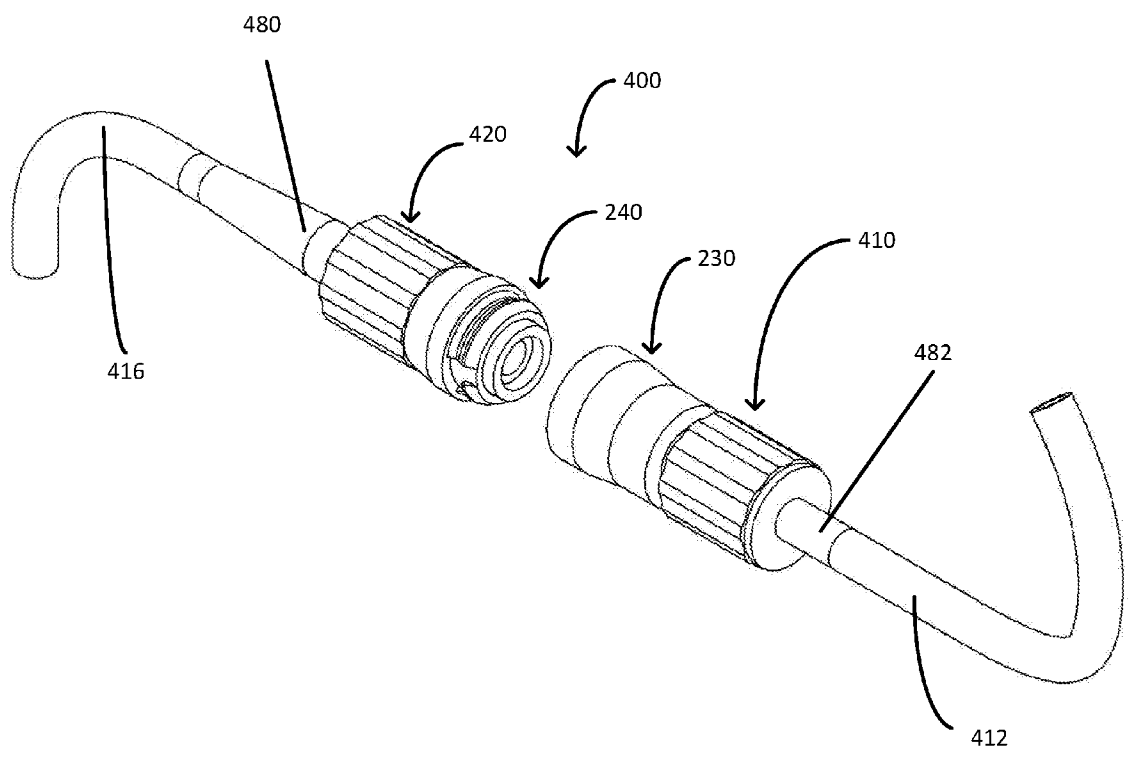

FIG. 23

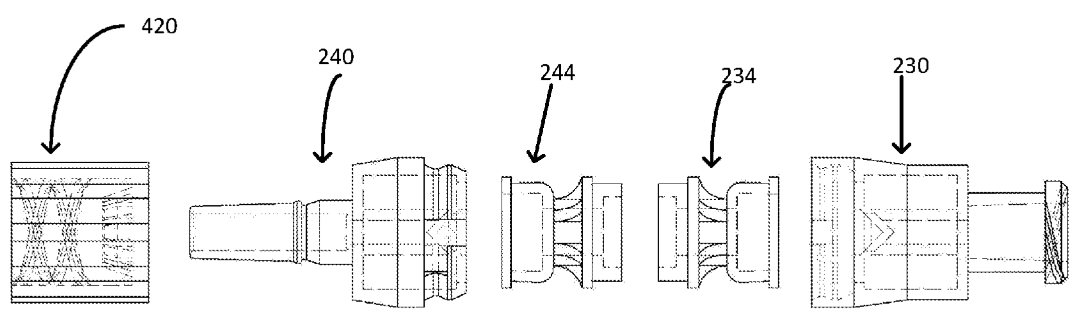

FIG. 24

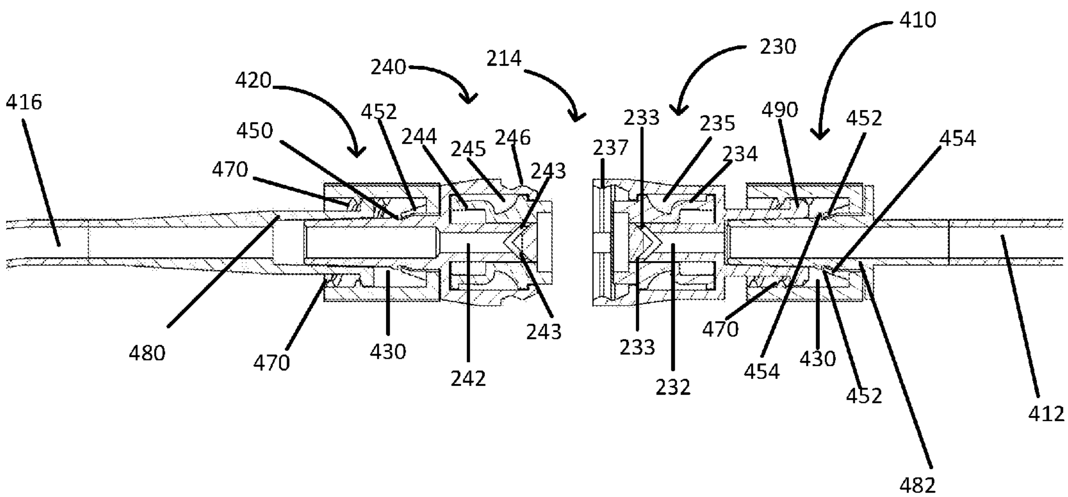
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FIG. 25

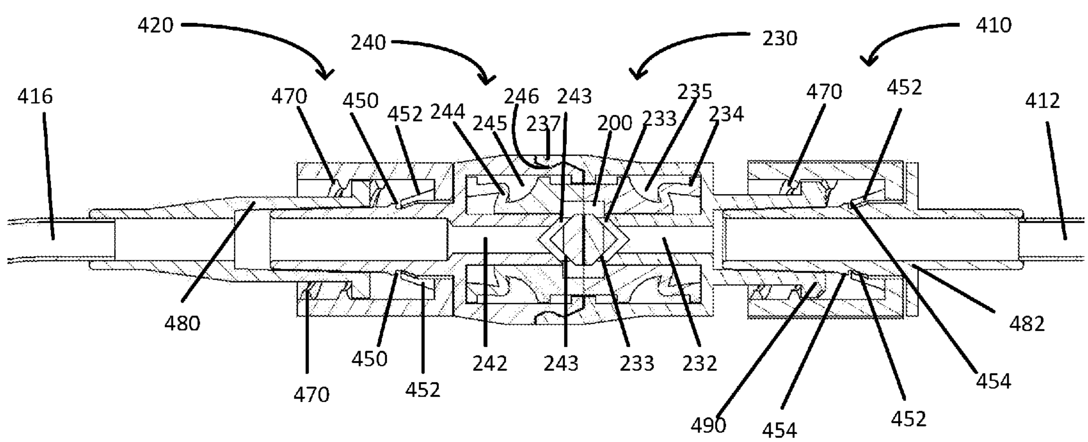
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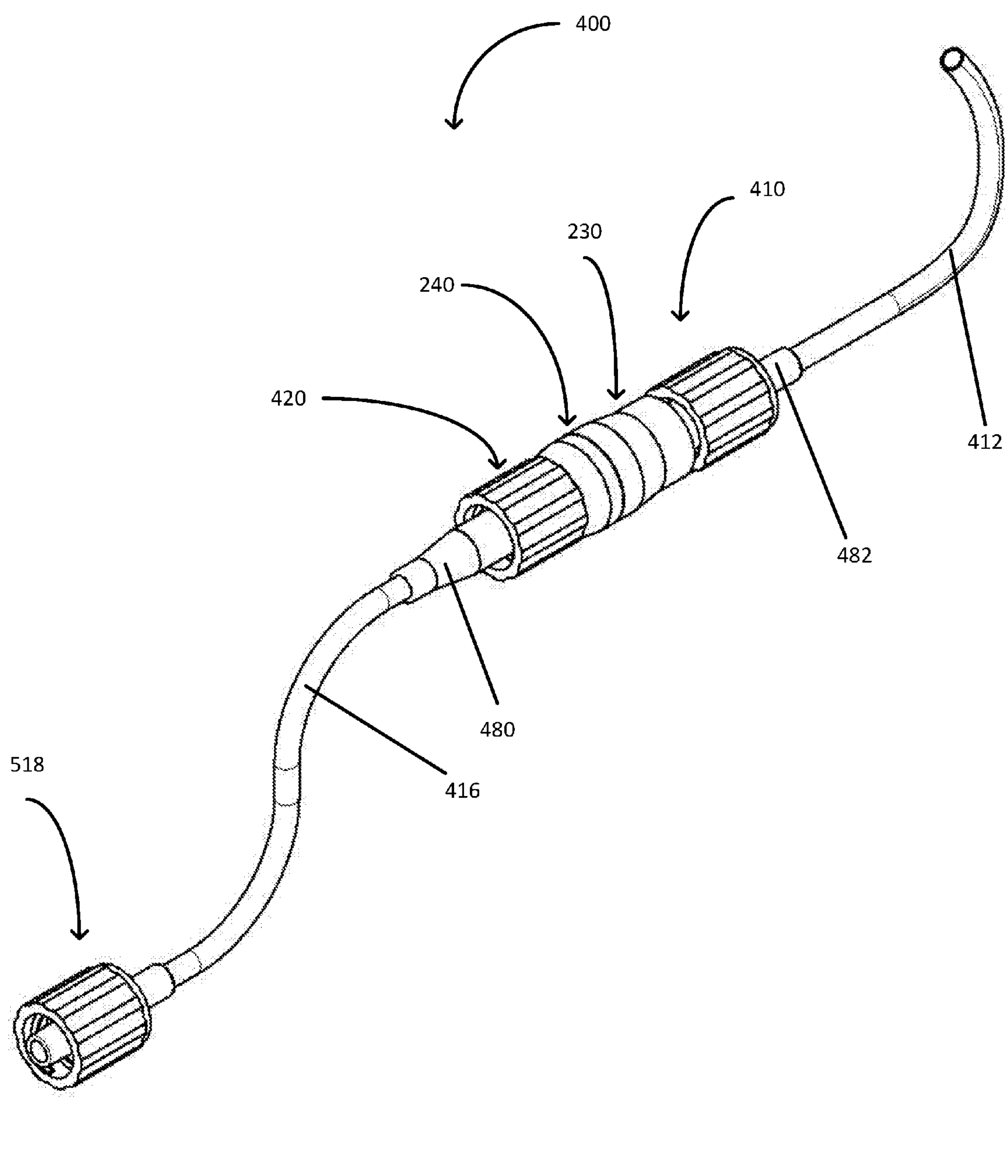
FIG. 26



TUBING SYSTEM

RELATED APPLICATIONS

This application claims the benefit of a provisional application, Application No. 62/183,996, filed Jun. 24, 2015.

FIELD OF THE INVENTION

The present invention is related to medical access devices, and more particularly to a a connect and disconnect system for medical tubing.

BACKGROUND OF THE INVENTION

Medical access devices are used in the treatment of hospitalized patients for a variety of purposes, including intravenous catheters, feeding tubes, Foley catheters, chest tubes, and a variety of surgical drains. Many of these medical access devices transport fluids from or to the patient and use a variety of flexible tubes to give the patient a range of movement during treatment. Unfortunately, due to the freedom of movement that some patients exhibit, the tubing associated with medical access devices is often subjected to forces that cause damage to the tubing, the patient, or both. For example, the tubing typically used in the administration of intravenous fluids is often several feet long, and accordingly can become entangled on hospital beds or other medical equipment surrounding the patient. As the patient moves, the tubing can be stretched. In extreme cases (which occur with astonishing frequency), the fluids being administered to the patient, or the patient's own body fluids can be spilled, creating a risk of contamination to the patient's treatment environment, and potentially exposing the patient to a risk of infection.

Thus there is a need for a system that prevents such damage caused by such forces. There is a further need for such a system that can be used with the variety of existing medical devices, without alteration to such medical devices. Such a system is described below.

BRIEF SUMMARY OF THE INVENTION

A tubing system includes a distal tubing assembly, a breakaway assembly, a proximal tubing assembly, and an adapter assembly. The distal tubing assembly includes a distal tubing connected to a fluid source and a first luer tip. The luer tip is inserted into the breakaway assembly, which includes a first breakaway subassembly and a second breakaway subassembly. The first breakaway subassembly includes a first fluid passageway that engages the luer tip of the distal tubing assembly, and an elastomeric first bellows sheath positioned within a first sheath channel. The second breakaway subassembly includes a second fluid passageway, a second bellows sheath positioned within a second sheath channel, a luer connector ring positioned within a luer connector channel. The first breakaway subassembly and second breakaway subassembly are initially connected with their respective sheaths aligned. A lock selectively engages to prevent disconnection of the breakaway subassemblies. The proximal tubing assembly includes a proximal tubing connected to a second luer tip, which in turn engages the luer connector ring of the second breakaway subassembly. The adapter assembly engages the proximal tubing assembly via its third fluid passageway. The adapter assembly also includes a luer tip with a flange that can engage and secure a standard luer connection.

An alternative embodiment of a breakaway assembly includes a first breakaway subassembly and a second breakaway subassembly. The first breakaway subassembly includes a first fluid passageway, a first bellows sheath, and a first sheath channel. The first fluid passageway has a first pore that is in communication with the first sheath channel. The first bellows sheath is positioned within the first sheath channel. The first bellows sheath is preferably made of an elastomeric substance. It will be understood that the first bellows sheath is capable of being compressed into at least two different positions, a first position in which the first bellows sheath seals the first pore and a second position in which the first bellows sheath permits fluid to pass through the first pore. The first breakaway subassembly also includes flanges for securing the first breakaway subassembly to the second breakaway subassembly. The second breakaway subassembly includes a second fluid passageway, a second bellows sheath, a second sheath channel, a plurality of connector ring flange slots, a luer connection. The second bellows sheath is positioned within the second sheath channel. The second bellows sheath is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. The second fluid passageway extends through the second breakaway subassembly such that fluid can flow through the first breakaway subassembly, into the second pore, and out to the second fluid passageway. Specifically, the second fluid passageway has a second pore that is in communication with the second sheath channel. The second bellows sheath is capable of being compressed into at least two different positions, a first position in which the second bellows sheath seals the second pore and a second position in which the second bellows sheath permits fluid to pass through the second pore and into the second fluid passageway.

An alternative embodiment of a tubing system for use with the first breakaway subassembly and the second breakaway subassembly in the alternative breakaway assembly includes a first luer connection assembly, a second luer connection assembly, a proximal tubing, second luer tip, a first luer tip, and a distal tubing. The first luer connection assembly connects to the first breakaway subassembly, and the second luer connection assembly connects to the second breakaway subassembly. While the first and second breakaway assemblies are the preferred embodiment for the connection of the first and second luer connection assemblies, it will be understood that other breakaway assemblies disclosed herein can be modified for use with the first and second luer connection assemblies. The preferred first luer connection assembly includes a flange, threads, and a luer connection channel. Similarly, the second luer connection assembly includes a flange, threads, and a luer connection channel. The flange of the first luer connection assembly slides into the flange acceptor of the first luer tip with sufficient force, securely connecting the first luer connection assembly to the first luer tip. The threads of the first luer connection assembly connect to the tab of the first breakaway subassembly, securely connecting the first luer connection assembly to the first breakaway subassembly. The distal tubing is friction fitted to the first luer tip. It will be understood that these components of the invention may be connected in any order. The flange of the second luer connection assembly slides into the notch of the second breakaway subassembly with sufficient force, securely connecting the second luer connection assembly to the second breakaway subassembly. The second luer tip is connected to the threads of the second luer connection assembly, securely attaching the second luer tip to the second luer connection assembly. The proximal tubing is friction fitted to the second luer tip. It will be understood that these components of the invention may be connected in any order. The flanges being connected to the notch and the flange acceptor allows for the quick disconnect and replacement of the components tubing system, which is very advantageous in the medical field.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. **1** A perspective view of a preferred tubing system.

FIG. **2** A perspective view of a preferred breakaway assembly in its disconnected state.

FIG. **3** An exploded side view of a preferred breakaway assembly, with internal structure depicted with dashed lines.

FIG. **4** A side cross-sectional view of a distal assembly, a preferred breakaway assembly in its disconnected state and a proximal assembly.

FIG. **5** A side cross-sectional view of a distal assembly, a preferred breakaway assembly in its connected state, and a proximal assembly.

FIG. **6** A perspective view of a preferred adapter assembly in its disconnected state.

FIG. **7** An exploded side view of a preferred adapter assembly.

FIG. **8** A side cross-sectional view of a preferred adapter assembly in its disconnected state.

FIG. **9** A side cross-sectional view of a preferred adapter assembly in its connected state.

FIG. **10** A side cross-sectional view of an alternative embodiment of the breakaway assembly in its disconnected state.

FIG. **11** A side cross-sectional view of an alternative embodiment of the breakaway assembly in its connected state.

FIG. **12** An exploded side view of an alternative embodiment of the breakaway assembly, with internal structure depicted with dashed lines.

FIG. **13** A side cross-sectional view of an alternative embodiment of the breakaway assembly in its connected state.

FIG. **14** A side view of an alternative embodiment of the second breakaway assembly.

FIG. **15** A side, cross-sectional view of an alternative embodiment of the second breakaway assembly.

FIG. **16** A perspective view of the of an alternative embodiment second breakaway assembly.

FIG. **17** A side view of the of an alternative embodiment first breakaway assembly, with internal structure depicted with dashed lines.

FIG. **18** A perspective view of the of an alternative embodiment first breakaway assembly.

FIG. **19** A side view of a bellows sheath with internal structure depicted with dashed lines.

FIG. **20** A perspective view of a bellows sheath.

FIG. **21** A partial cross-section view of a bellows sheath.

FIG. **22** A perspective view of an alternative embodiment of a tubing system, disconnected.

FIG. **23** A side view of an alternative embodiment of a second luer connection assembly, with a first breakaway assembly, a second breakaway assembly, and bellows sheaths **234**, **244** of the embodiment of FIGS. **13-21**, with internal structure depicted with dashed lines.

FIG. **24** A side cross sectional view of the alternative embodiment of a tubing system, with the first breakaway assembly and second breakaway assembly disconnected.

FIG. **25** A side cross sectional view of the alternative embodiment of a tubing system, with the first breakaway assembly and second breakaway assembly connected.

FIG. **26** A perspective view of the alternative embodiment of a tubing system, connected.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** shows a preferred embodiment of a tubing system **10** including a distal assembly **12**, a breakaway assembly **14**, a proximal assembly **16**, and an adapter assembly **18**. As depicted, the assemblies are connected in succession to each other.

Turning to FIG. **4**, the preferred distal assembly **12** preferably includes a distal tubing **20** and a first luer tip **22**. The first luer tip **22** is friction fitted on one end of the distal tubing **20** as shown. The distal tubing **20** is connected to a fluid source (not shown). In the preferred embodiment, the fluid source is a container of an intravenous solution. In alternative embodiments the fluid source is an intracorporeal portion of a drain or tube. It will be understood by those skilled in the art that in other embodiments an infusion pump or other apparatus may be positioned between the distal assembly **12** and the fluid source.

Turning to FIGS. **2-5**, the breakaway assembly **14** includes a first breakaway subassembly **30** and a second breakaway subassembly **40**. FIG. **3** depicts the first breakaway subassembly **30** including a first fluid passageway **32**, a first bellows sheath **34**, a first sheath channel **35**, a first connector ring **36**, and a lock ring **38**. In the depicted embodiment, the first fluid passageway **32** is configured to receive the first luer tip **22** such that fluid from the distal assembly **12** flows through the first luer tip **22** and into the first fluid passageway **32**. The first fluid passageway **32** has a first pore **33** that is in communication with the first sheath channel **35**. The first bellows sheath **34** is positioned within the first sheath channel **35**. The first bellows sheath **34** is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. It will be understood that the first bellows sheath is capable of being compressed into at least two different positions, a first position in which the first bellows sheath **34** seals the first pore **33** (as shown in FIG. **4**) and a second position in which the first bellows sheath **34** permits fluid to pass through the first pore **33** (as shown in FIG. **5**). In the depicted embodiment, the first connector ring **36** includes a plurality of finger flanges **37** (shown in FIG. **3**). The first connector ring **36** is positioned around an exterior surface of the first breakaway subassembly **30**.

The second breakaway subassembly **40** includes a second fluid passageway **42**, a second bellows sheath **44**, a second sheath channel **45**, a plurality of connector ring flange slots **46**, a luer connection channel **47**, a luer connector ring **48**, a spring **51**, a luer release button **52**, an interior plate **53** and a lock post **145**. The second bellows sheath **44** is positioned within the second sheath channel **45**. The second bellows sheath **44** is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. The luer connection channel **47** is positioned within the second breakaway subassembly **40** and is separated from the second sheath channel **45** by the interior plate **53**. The luer connection channel **47** is configured to receive the spring **51** and the luer connector ring **48**. The spring **51** is positioned within the luer connection channel **47** and abuts the interior plate **53**. The luer connector ring **48** includes a release tab **49** and a plurality of luer connection flanges **50**, and is positioned within the luer connection channel **47**, pressing against the spring **51**. It will be understood that as the luer connector ring **48** is pressed within the luer connection channel **47**, the spring **51** is compressed against the interior plate **53**. With sufficient force, the luer connector ring **48** can be pressed into the luer connection channel **47** such that the release tab **49** engages a complementary geometric protrusion of the luer release button **52**, as shown in FIGS. **4** and **5**. It will be further understood that when the release tab **49** engages the luer release button **52**, the luer connector ring **38** is secured within the luer connection channel **47** despite the force exerted by the spring **51** against the luer connector ring **38**. The second fluid passageway extends through the second breakaway subassembly **40** such that fluid from the distal assembly **12** can flow through the first breakaway subassembly **30**, into the second pore **43**, and out to the proximal assembly **16**. Specifically, the second fluid passageway **42** has a second pore **43** that is in communication with the second sheath channel **45**. The second bellows sheath **44** is capable of being compressed into at least two different positions, a first position in which the second bellows sheath **44** seals the second pore **43** (as shown in FIG. **4**) and a second position in which the second bellows sheath **44** permits fluid to pass through the second pore **43** (as shown in FIG. **5**).

The first breakaway subassembly **30** and the second breakaway subassembly **40** may be connected by aligning the first bellows sheath **34** with second bellows sheath **44** and pressing the two breakaway subassemblies together such that the finger flanges **37** of the first connector ring **36** engage the connector ring flange slots **46** that are positioned around the exterior of the second breakaway subassembly **40**, as shown in FIG. **5**. It will be understood that when the two breakaway subassemblies **30**, **40** are connected in this manner, the first bellow sheath **34** is compressed into the first sheath channel **35** in a manner that unseals the first pore **33**. Similarly, the second bellows sheath **44** is compressed in the second sheath channel **45** thereby unsealing the second pore **43**. When the two breakaway subassemblies **30**, **40** are connected in this manner, a fluid path **100** is created that permits fluid to flow from the first fluid passageway **32** through the fluid path **100** and into the second fluid passageway **42**, as shown in FIG. **5**.

Now the first breakaway subassembly **30** and second breakaway subassembly **40** may be disconnected when a sufficient force is applied to dislodge the finger flanges **37** of the first connector ring **36** from the connector ring flange slots **46**. When the two breakaway subassemblies **30**, **40** are disconnected, the first pore **33** is sealed off as the first bellows sheath **34** expands within the first sheath channel **35**. Similarly, the second pore **43** is sealed off as the second bellows sheath **44** expands within the second sheath channel **45**. It will be understood that this creates a self-sealing system, such that if an accidental disconnection occurs, the breakaway assembly **14** will seal the fluid path in such a way that no fluid escapes the tubing system **10**.

It will be understood that the lock ring **38** of the first breakaway subassembly **30** can be adjusted circumferentially to engage or disengage the lock post **145** of the second breakaway subassembly **40** to achieve two states: a first state in which the breakaway subassemblies **30**, **40** cannot be separated, and a second state that permits disconnection upon application of a sufficient force, which normally is 5 to 7 pounds of tension force. It will be further understood that to promote judicious infection control, reconnection of the subassemblies **30**, **40** is discouraged. Preferably, the breakaway assembly **14** is delivered to the user in a connected state. In the event a force is applied to disconnect the two breakaway subassemblies **30**, **40** from each other, the finger flanges **37** of the first breakaway subassembly **30** are configured to flex inward towards the central radius of the first breakaway subassembly **30** such that they can no longer clear the diameter of the second breakaway subassembly **40** to engage the connector ring flange slots **46**. This preferred mechanism prevents the breakaway subassemblies **30**, **40** from being reconnected after they are initial disconnected.

The preferred proximal assembly **16** includes a second luer tip **60** and a proximal tubing **61**. The proximal tubing **61** is flush fitted within the second luer tip **60**. The second luer tip **60** engages the plurality of luer connection flanges **50** which secure the second luer tip **60** to the second breakaway subassembly **40** when the luer connector ring **48** is second within the luer connection channel **47**.

FIG. **6** depicts the adapter assembly **18**, which preferably includes a luer connector assembly **80**, which engages a standard luer tip **90**. Turning to FIG. **7**, the luer connector assembly **80** includes an interior plate **81**, a third fluid passageway **82**, a luer connector ring **84**, a luer connection channel **87**, a luer release button **88**, and a spring outside the fluid path **89**.

The luer connection channel **87** is configured to receive the spring **89** and the luer connector ring **84**. The spring **89** is positioned within the luer connection channel **87** and abuts the interior plate **81**. The luer connector ring **84** includes a release tab **85** and a plurality of luer connection fingers **86**, and is positioned within the luer connection channel **87**, pressing against the spring **89**. It will be understood that as the luer connector ring **84** is pressed within the luer connection channel **87**, the spring **89** is compressed against the interior plate **81**. With sufficient force, the luer connector ring **84** can be pressed into the luer connection channel **87** such that the release tab **85** engages the luer release button **88**, as shown in FIG. **9**. It will be further understood that when the release tab **85** engages the luer release button **88**, the luer connector ring **84** is secured within the luer connection channel **87** despite the force exerted by the spring **89** against the luer connector ring **84**. The third fluid passageway **82** extends through the luer connector assembly **80** such that fluid from the proximal assembly **16** flows through the luer connector assembly **80**.

FIGS. **8** and **9** show the luer tip **90**, which includes a connection flange **91**. Those skilled in the art will recognize that the luer tip **90** is standard luer tip used in typical catheter assembles known in the art. It will be understood that as a standard luer tip **90** engages the luer connector assembly **80**, the plurality of luer connection fingers **86** engage the connection flange **91**, and that as the luer tip **90** and luer connector ring **84** are pressed further into the channel, the luer connection fingers **86** are forced down behind the connection flange **91**. In this manner a luer tip **90** is secured to the luer connector assembly **80**.

Other alternative embodiments of each aspect of the disclosed tubing system **10** are possible. For example FIGS. **10** and **11** depict such an alternative embodiment, wherein the elastomeric first and second bellows sheaths are replaced with pusher plates **134**, **144** and springs **135**, **136**.

Yet another alternative embodiment of a breakaway assembly **214** is shown in FIG. **13**, which includes a first breakaway subassembly **230** and a second breakaway subassembly **240**. The first breakaway subassembly **230** includes a first fluid passageway **232**, a first bellows sheath **234**, and a first sheath channel **235**. The first fluid passageway **232** has a first pore **233** that is in communication with the first sheath channel **235**. The first bellows sheath **234** is positioned within the first sheath channel **235**. The first bellows sheath **234** is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. It will be understood that the first bellows sheath is capable of being compressed into at least two different positions, a first position in which the first bellows sheath **234** seals the first pore **233** (as shown in FIGS. **4** and **24**) and a second position in which the first bellows sheath **234** permits fluid to pass through the first pore **233** (as shown in FIGS. **5**, **13** and **25**). The first breakaway subassembly **230** also includes flanges **237** for securing the first breakaway subassembly **230** to the second breakaway subassembly **240**.

The second breakaway subassembly **240** includes a second fluid passageway **242**, a second bellows sheath **244**, a second sheath channel **245**, a plurality of connector ring flange slots **246**, a luer connection **247**. The second bellows sheath **244** is positioned within the second sheath channel **245**. The second bellows sheath **244** is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. The second fluid passageway **242** extends through the second breakaway subassembly **240** such that fluid can flow through the first breakaway subassembly **230**, into the second pore **243**, and out to the second fluid passageway **242**. Specifically, the second fluid passageway **242** has a second pore **243** that is in communication with the second sheath channel **245**. The second bellows sheath **244** is capable of being compressed into at least two different positions, a first position in which the second bellows sheath **244** seals the second pore **243** (as shown in FIGS. **4** and **24**) and a second position in which the second bellows sheath **244** permits fluid to pass through the second pore **243** and into the second fluid passageway **242** (as shown in FIGS. **5**, **13** and **25**).

In the alternative embodiment depicted in FIGS. **13-21**, it will be understood that no proximal assembly **60** (as shown in FIGS. **2** and **4-5**) is needed as the second breakaway subassembly **240** includes a luer connection **247** that is in communication with the second fluid passageway **242** and is configured to accept a connection with typical luer locks **300** used in the field and known to those skilled to those in the art.

The first breakaway subassembly **230** and the second breakaway subassembly **240** may be connected by aligning the first bellows sheath **234** with second bellows sheath **244** and pressing the two breakaway subassemblies together such that the finger flanges **237** engage flange slots **246** that are positioned around the exterior of the second breakaway subassembly **240**, as shown in FIG. **13**. It will be understood that when the two breakaway subassemblies **230**, **240** are connected in this manner, the first bellow sheath **234** is compressed into the first sheath channel **235** in a manner that unseals the first pore **233**. Similarly, the second bellows sheath **244** is compressed in the second sheath channel **245** thereby unsealing the second pore **243**. When the two breakaway subassemblies **230**, **240** are connected in this manner, a fluid path **200** is created that permits fluid to flow from the first fluid passageway **232** through the fluid path **200** and into the second fluid passageway **242**, as shown in FIG. **13**. It should be noted that flow of the fluid path **200** is not obstructed by the operation of the bellows sheaths **234**, **244** because the bellows sheaths are outside of the flow path of the fluids.

The first breakaway subassembly **230** and second breakaway subassembly **240** may be disconnected when a sufficient force, which normally is 5 to 7 pounds of tension force, is applied to dislodge the finger flanges **237** from the flange slots **246**. When the two breakaway subassemblies **230**, **240** are disconnected, the first pore **233** is sealed off as the first bellows sheath **234** expands within the first sheath channel **235**. Similarly, the second pore **243** is sealed off as the second bellows sheath **44** expands within the second sheath channel **245**. It will be understood that this creates a self-sealing system, such that if an accidental disconnection occurs, the breakaway assembly **214** will seal the fluid path in such a way that no fluid escapes the tubing system **10**.

The first breakaway subassembly **230** and the second breakaway subassembly **240** may also be locked into place. As shown in FIG. **17**, the first breakaway subassembly **230** also includes a locking tab **220**. The locking tab **220** is configured to be inserted into a locking slot **210** on the second breakaway subassembly **240**, shown in FIG. **15**. The locking slot **210** is configured so that when the locking tab **220** is inserted into the locking slot **210** and the first breakaway subassembly **230** is rotated relative to the section breakaway subassembly **240**, the first breakaway subassembly **230** and the second breakaway subassembly are locked together. While locking the first breakaway subassembly **230** to the second breakaway subassembly **240** is possible, it is not necessary for the invention to perform its purpose as described above. It will be understood that the invention can be engaged in two separate states: a first state where the first breakaway subassembly **230** cannot be disconnected from the second breakaway subassembly **240** because the locking tab **220** is engaged and rotated into the locking slot **210**; and a second state where sufficient force (which is normally between 5 and 7 lbs. of tension force) allows disconnection of the first breakaway subassembly **230** and the second breakaway subassembly **240**. It will be understood that in the first state, the first breakaway subassembly **230** and the second breakaway subassembly **240** must be rotated in opposite directions to unlock the device before the finger flanges **237** can be dislodges from the flange slots **246**.

The second breakaway subassembly **240** is further shown in a disconnected state in FIGS. **14**, **15**, and **16**. The second breakaway assembly **240** of FIGS. **14** and **16** include flange slots **246**, the locking slot **210**, and a second luer tip connection **260**. FIG. **15** shows a second breakaway assembly **240** that includes second bellows sheath channel **245**, second pore **243**, and second fluid passageway **242**.

The first breakaway subassembly **230** is further shown in a disconnected state in FIGS. **17** and **18**. The first breakaway assembly **230** of FIG. **17** includes finger flanges **237**, a locking tab **220**, a first fluid passageway **232**, first bellows sheath channel **235**, a first luer connection **222**, and pores **233**. The first breakaway assembly **230** of FIG. **18** includes finger flanges **237**, locking mechanisms **220**, and a first luer connection **222**.

FIGS. **19**, **20**, and **21** show the bellows sheaths **234**, **244** in the state when the first breakaway subassembly **230** and the second breakaway subassembly **240** are disconnected, as in FIGS. **14-18**. When a force is applied to the first breakaway subassembly **230** and the second breakaway subassembly **240** during connection, the bellows sheaths **234**, **244** compress, resulting in the opening of the pores **233**, **243** (shown in FIG. **13**). Once the pores **233**, **243** open, the fluid may flow through the subassemblies **230**, **240**.

Importantly, in the preferred and alternative embodiments of the tubing system **10**, **400**, all components are made of non-metallic substances, such as plastic and elastomeric substances, which is beneficial for imaging and other procedures in the medical field that prohibit the use of metallic substances during those procedures.

An alternative embodiment of a tubing system **400** for use with the first breakaway subassembly **230** and the second breakaway subassembly **240**, as illustrated in FIGS. **13-21** and detailed above, is shown in FIG. **22**. The tubing system **400** includes a first luer connection assembly **410**, a second luer connection assembly **420**, a proximal tubing **416**, second luer tip **480**, a first luer tip **482**, and a distal tubing **412**. The first luer connection assembly **410** connects to the first breakaway subassembly **230**, and the second luer connection assembly **420** connects to the second breakaway subassembly **240**. While the first and second breakaway assemblies **230**, **240** are the preferred embodiment for the connection of the first and second luer connection assemblies **410**, **420**, it will be understood that other breakaway assemblies disclosed herein can be modified for use with the first and second luer connection assemblies **410**, **420**.

Turning to FIG. **24**, the first breakaway subassembly **230** includes a first fluid passageway **232**, a first bellows sheath **234**, a notch **450**, and a first sheath channel **235**. The first fluid passageway **232** has a first pore **233** that is in communication with the first sheath channel **235**. The first bellows sheath **234** is positioned within the first sheath channel **235**. The first bellows sheath **234** is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. It will be understood that the first bellows sheath is capable of being compressed into at least two different positions, a first position in which the first bellows sheath **234** seals the first pore **233** (as shown in FIG. **24**) and a second position in which the first bellows sheath **234** permits fluid to pass through the first pore **233** (as shown in FIG. **25**). The first breakaway subassembly **230** also includes flanges **237** for securing the first breakaway subassembly **230** to the second breakaway subassembly **240**.

The second breakaway subassembly **240** includes a second fluid passageway **242**, a second bellows sheath **244**, a second sheath channel **245**, a plurality of connector ring flange slots **246**, a notch, and a luer connection channel **247**. The second bellows sheath **244** is positioned within the second sheath channel **245**. The second bellows sheath **244** is preferably made of an elastomeric substance. The elastomeric substance is preferably USP class VI liquid silicone rubber. The second fluid passageway **242** extends through the second breakaway subassembly **240** such that fluid can flow through the first breakaway subassembly **230**, into the second pore **243**, and out to the second fluid passageway **242**. Specifically, the second fluid passageway **242** has a second pore **243** that is in communication with the second sheath channel **245**. The second bellows sheath **244** is capable of being compressed into at least two different positions, a first position in which the second bellows sheath **244** seals the second pore **243** (as shown in FIG. **24**) and a second position in which the second bellows sheath **244** permits fluid to pass through the second pore **243** and into the second fluid passageway **242** (as shown in FIG. **25**). The operation and connection of the breakaway subassemblies **230**, **240** are explained in more detail above.

The preferred first luer connection assembly **410** includes a flange **452**, threads **470**, and a luer connection channel **430**. Similarly, the second luer connection assembly **420** includes a flange **452**, threads **470**, and a luer connection channel **430**.

The flange **452** of the first luer connection assembly **410** slides into the flange acceptor **454** of the first luer tip **482** with sufficient force, securely connecting the first luer connection assembly **410** to the first luer tip **482**. The threads **470** of the first luer connection assembly **410** connect to the tab **490** of the first breakaway subassembly **230**, securely connecting the first luer connection assembly **410** to the first breakaway subassembly **230**. The distal tubing **416** is friction fitted to the first luer tip **482**. It will be understood that these components of the invention may be connected in any order.

The flange **452** of the second luer connection assembly **420** slides into the notch **450** of the second breakaway subassembly **240** with sufficient force, securely connecting the second luer connection assembly **420** to the second breakaway subassembly **240**. The second luer tip **480** is connected to the threads **470** of the second luer connection assembly **420**, securely attaching the second luer tip **480** to the second luer connection assembly. The proximal tubing **416** is friction fitted to the second luer tip **480**. It will be understood that these components of the invention may be connected in any order.

The flanges **452** being connected to the notch **452** and the flange acceptor **454** allows for the quick disconnect and replacement of the components tubing system **400**, which is very advantageous in the medical field.

Turning to FIG. **25** shows the embodiment of FIG. **24**, but displays the connection of the first breakaway assembly **230** and the second breakaway assembly **240**.

FIG. **26** shows the embodiment of FIG. **25**, with the addition of a luer adaptor **518**.

FIG. **23** shows a first breakaway subassembly **230**, a second breakaway subassembly **240**, a first bellows sheath **234**, a second bellows sheath **244**, and a second luer connection assembly **420**. One should appreciate that the bellows sheaths **234**, **244** have been removed from the first breakaway subassembly **230** and the second breakaway subassembly **240** in FIG. **23** for illustration purposes.

It is clear that the present invention is well adapted to carry out its objectives and attain the ends and advantages mentioned above as well as those inherent therein. While presently preferred embodiments of the invention have been described in varying detail for purposes of disclosure, it will be understood that numerous changes may be made which will readily suggest themselves to those skilled in the art and which are encompassed within the spirit of the invention disclosed herein.

We claim:

1. An assembly for use in medical tubing, the assembly comprising:

- a first subassembly comprising:
  - a first fluid passageway disposed within a first inner annular extension having an end with a first pore, wherein the first pore is substantially perpendicular to the first fluid passageway; and
  - a first bellows sheath made of an elastomeric substance and positioned around the first inner annular extension, the first bellows sheath configured to selectively prevent fluid from exiting the first fluid passageway when the first bellows sheath is in a first position and configured to permit fluid to exit from the first fluid passageway when the first bellows sheath is in a second position; and
- a second subassembly configured to engage the first subassembly, the second subassembly comprising:
  - a second fluid passageway disposed within a second inner annular extension having an end with a second pore, wherein the second pore is substantially perpendicular to the second fluid passageway; and
  - a second bellows sheath made of an elastomeric substance and positioned around the second inner annular extension, the second bellows sheath configured to selectively prevent fluid from entering the second

fluid passageway when the second bellows sheath is in a first position and configured to permit fluid to enter into the second fluid passageway when the second bellows sheath is in a second position; and

wherein an engagement of the first subassembly with the second subassembly causes the first bellows sheath to move from its first position to its second position, and causes the second bellows sheath to move from its first position to its second position;

wherein a disengagement of the first subassembly and the second subassembly causes the first bellows sheath to move from its second position to its first position, and causes the second bellows sheath to move from its second position to its first position;

wherein the first subassembly and second subassembly can be selectively locked to prevent disengagement.

2. The assembly of claim **1** wherein the elastomeric substance is USP class VI silicone rubber.

3. The assembly of claim **1**, wherein the assembly is manufactured from non-metallic materials.

4. A method for connecting medical tubing to a patient, the method comprising the steps of:

connecting a distal assembly to a first breakaway subassembly;

connecting a proximal assembly to a second breakaway subassembly;

connecting the first breakaway subassembly to the second breakaway subassembly, wherein the connection of the first breakaway subassembly and the second breakaway subassembly compresses a first bellows sheath positioned around a first inner annular extension of the first breakaway assembly and compresses a second bellows sheath positioned around a second inner annular extension the second breakaway subassembly; and

connecting the first breakaway subassembly with the second breakaway subassembly by engaging flanges on the first breakaway subassembly with flange slots on the second breakaway subassembly;

wherein the compression of the first bellows sheath and the second bellows sheath permits fluid to flow from the distal assembly through the first inner annular extension of the first breakaway assembly and into the second inner annular extension of the second breakaway assembly and into the proximal assembly.

5. The method of claim **4**, wherein the step of connecting the first breakaway assembly and the second breakaway assembly requires an insertion of a locking tab into a locking slot.

6. The method of claim **5**, further comprising the step of connecting the proximal assembly to a patient.

7. The method of claim **6**, wherein the distal assembly, the first breakaway assembly, the second breakaway assembly, and the proximal assembly are manufactured from non-metallic materials.

8. The method of claim **4**, wherein the first bellows sheath and the second bellows sheath are substantially the same shape.

9. The method of claim **4**, wherein the first bellows sheath and the second bellows sheath are both cylindrically shaped and have substantially the same length, diameter, and thickness.

10. The method of claim **4**, wherein the first bellows sheath and the second bellows sheath have substantially the same cross-sectional shape.

11. An assembly for use in medical tubing, the assembly comprising:

a breakaway subassembly comprising:

a fluid passageway disposed within an inner annular extension; and

a bellows sheath positioned around the inner annular extension, the bellows sheath configured to selectively prevent fluid from entering the fluid passageway when the bellows sheath is in a first position and configured to permit fluid to enter into the fluid passageway when the bellows sheath is in a second position; and

a notch;

a luer connection subassembly comprising:

a luer connection subassembly body;

a luer connection channel positioned within the luer connection subassembly body;

a flange positioned within the luer connection channel and connected to the luer connection subassembly body;

at least one thread positioned within the luer connection channel and connected to the luer connection subassembly body; and

a second breakaway subassembly comprising:

a second fluid passageway disposed within a second inner annular extension; and

a second bellows sheath positioned around the second inner annular extension, the second bellows sheath configured to selectively prevent fluid from entering the second fluid passageway when the second bellows sheath is in a first position and configured to permit fluid to enter into the second fluid passageway when the second bellows sheath is in a second position;

wherein the bellows sheath and the second bellows sheath are substantially the same shape;

wherein the flange of the luer connection subassembly can selectively engage the notch of the breakaway subassembly to secure the luer connection subassembly to the breakaway subassembly.

12. The assembly of claim **11**, wherein the bellows sheath is made of an elastomeric substance.

13. The assembly of claim **12**, wherein the elastomeric substance is USP class VI liquid silicone rubber.

14. The assembly of claim **13**, wherein the assembly is manufactured from non-metallic materials.

15. The assembly of claim **11**, wherein the bellows sheath and the second bellows sheath are both cylindrically shaped and have substantially the same length, diameter, and thickness.

16. The assembly of claim **11**, wherein bellows sheath and the second bellows sheath have substantially the same cross-sectional shape.

17. An assembly for use in medical tubing, the assembly comprising:

a first subassembly comprising:

a first fluid passageway disposed within a first inner annular extension; and

a first bellows sheath positioned around the first inner annular extension, the first bellows sheath configured to selectively prevent fluid from exiting the first fluid passageway when the first bellows sheath is in a first position and configured to permit fluid to exit from the first fluid passageway when the first bellows sheath is in a second position; and

a second subassembly configured to engage the first subassembly, the second subassembly comprising:

a second fluid passageway disposed within a second inner annular extension; and

a second bellows sheath positioned around the second inner annular extension, the second bellows sheath configured to selectively prevent fluid from entering the second fluid passageway when the second bellows sheath is in a first position and configured to permit fluid to enter into the second fluid passageway when the second bellows sheath is in a second position;

wherein the first bellows sheath and the second bellows sheath are substantially the same shape.

18. An assembly for use in medical tubing, the assembly comprising:

a first subassembly comprising:

a first fluid passageway disposed within a first inner annular extension; and

a first bellows sheath positioned around the first inner annular extension, the first bellows sheath configured to selectively prevent fluid from exiting the first fluid passageway when the first bellows sheath is in a first position and configured to permit fluid to exit from the first fluid passageway when the first bellows sheath is in a second position; and

a second subassembly configured to engage the first subassembly, the second subassembly comprising:

a second fluid passageway disposed within a second inner annular extension; and

a second bellows sheath positioned around the second inner annular extension, the second bellows sheath configured to selectively prevent fluid from entering the second fluid passageway when the second bellows sheath is in a first position and configured to permit fluid to enter into the second fluid passageway when the second bellows sheath is in a second position;

wherein the first bellows sheath and the second bellows sheath are both cylindrically shaped and have substantially the same length, diameter, and thickness.

19. An assembly for use in medical tubing, the assembly comprising:

a first subassembly comprising:

a first fluid passageway disposed within a first inner annular extension; and

a first bellows sheath positioned around the first inner annular extension, the first bellows sheath configured to selectively prevent fluid from exiting the first fluid passageway when the first bellows sheath is in a first position and configured to permit fluid to exit from the first fluid passageway when the first bellows sheath is in a second position; and

a second subassembly configured to engage the first subassembly, the second subassembly comprising:

a second fluid passageway disposed within a second inner annular extension; and

a second bellows sheath positioned around the second inner annular extension, the second bellows sheath configured to selectively prevent fluid from entering the second fluid passageway when the second bellows sheath is in a first position and configured to permit fluid to enter into the second fluid passageway when the second bellows sheath is in a second position;

wherein the first bellows sheath and the second bellows sheath have substantially the same cross-sectional shape.

20. An assembly for use in medical tubing, the assembly comprising:

a first subassembly comprising:

a first inner annular extension;

a first fluid passageway disposed within the first inner annular extension and configured to receive fluid;

a first outer annular extension positioned around the first inner annular extension;

a first bellows sheath positioned between the first inner annular extension and the first outer annular extension;

the first bellows sheath having a first position and a second position, wherein the first position prevents fluid from exiting the first fluid passageway and the second position permits fluid to exit the first fluid passageway; and

wherein compression of the first bellows sheath reconfigures it from its first position to its second position;

a second subassembly comprising:

a second inner annular extension;

a second fluid passageway disposed within the second inner annular extension and configured to receive fluid;

a second outer annular extension positioned around the second inner annular extension;

a second bellows sheath positioned between the second inner annular extension and the second outer annular extension;

the second bellows sheath having a first position and a second position, wherein the first position prevents fluid from entering the second fluid passageway and the second position permits fluid to enter the second fluid passageway; and

wherein compression of the second bellows sheath reconfigures it from its first position to its second position;

wherein an engagement of the first subassembly with the second subassembly compresses the first bellows sheath and compresses the second bellows sheath;

wherein the first bellows sheath and the second bellows sheath are substantially the same shape.

21. The assembly of claim **20**, wherein a disengagement of the first subassembly from the second subassembly decompresses the first bellows sheath from its second position to its first position and decompresses the second bellows sheath to from its second position to its first position.

22. The assembly of claim **20**, wherein the first bellows sheath and the second bellows sheath have substantially the same length, diameter, and thickness.

23. The assembly of claim **20**, wherein the first bellows sheath and the second bellows sheath have substantially the same cross-sectional shape.

24. The assembly of claim **21**, wherein the first subassembly and second assembly can be selectively locked to prevent the disengagement of the first subassembly from the second subassembly.

25. The assembly of claim **21**, wherein the assembly is manufactured from non-metallic materials.

26. The assembly of claim **21**, wherein the first bellows sheath and the second bellows sheath are made of an elastomeric substance.

27. The assembly of claim **26**, wherein the elastomeric substance is USP class VI liquid silicone rubber.

28. The assembly of claim **20**, wherein the first subassembly further comprises a first pore extending through a distal portion of the first inner annular extension.

29. The assembly of claim **28**, wherein the first bellows sheath in its first position prevents fluid from entering the first fluid passageway by sealing the first pore.

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